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U.S. NEWS

Surgeons Eyed Over Deals With Medical-Device Makers

Justice Department Investigation Shines Light on Federal Authorities' Broader Scrutiny of Physician-Owned Distributorships

By JOHN CARREYROU

July 25, 2013 11:01 p.m. ET

Ten months after an Afghan-born surgeon named Aria Sabit arrived in Ventura, Calif., local hospital staffers noticed he suddenly developed a preference for an obscure brand of spinal implants for many of his surgeries. Soon his volume of operations increased, with sometimes-tragic results.



Dr. Aria Sabit, a spinal surgeon, testifying in a deposition last year. *Glickman & Glickman*

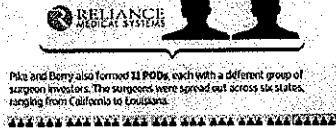


The late Lilian Kaulback was operated on by Dr. Sabit in October 2010 with Apex implants. *Kevin Reynolds*

In the Network

Physician-owned distributorships, or PODs, enable surgeons to profit from their use of medical devices. Typically, the identities of the physician owners aren't disclosed to the public. The Reliance network comprised a parent company that manufactured devices and 11 sister PODs that sold them.

Parent company Reliance Medical Systems was formed by Adam Pika and Brett Berry to make spinal implants.



Pika and Berry also formed 11 PODs, each with a different group of surgeon investors. The surgeons were spread out across six states, ranging from California to Louisiana.

By the time he moved on less than a year later in late 2010, he had become embroiled in investigations by the California medical board and the Food and Drug Administration and more than two dozen medical malpractice lawsuits, including 12 involving surgeries he did with the new implants.

Now, the Department of Justice is investigating Dr. Sabit because it has emerged that he had an ownership interest in the company that distributed, and profited from, the surgical devices he switched to, people familiar with the matter say.

Federal prosecutors' scrutiny of Dr. Sabit is part of a broader civil investigation into a network of physician-owned spinal-implant distributorships operated by two former medical-device company employees, the people with knowledge of the matter say. This network, which was run out of Utah and comprised at least 11 physician-owned distributorships in six states, generated tens of millions of dollars in profits for its investors over six years.

Physician-owned distributorships, or PODs, have proliferated in medicine. Distributorships, whether owned by physicians or not, act as intermediaries between medical-device makers and hospitals: In exchange for marketing and stocking devices, the distributors get a cut of each sale. When surgeons own the distributorship, that commission goes into their pockets. And since surgeons often dictate to their hospitals which devices to buy, they can effectively steer business to themselves.

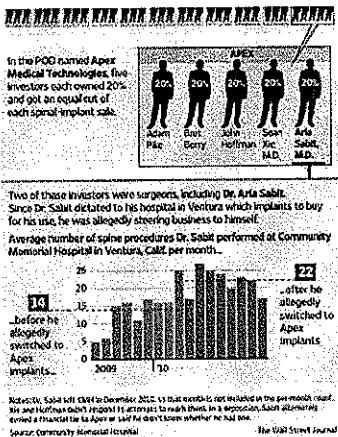
Depending on how they are set up, such entities can be legal. But in March, the Department of Health and Human Services' Office of Inspector General issued a special fraud alert about PODs, warning that they "pose dangers to patient safety" by inducing surgeons to do more procedures than necessary and to favor devices they profit from over more "clinically appropriate" ones.

In Dr. Sabit's case, the Justice Department has been looking into whether his financial interest in the implants caused him to over-operate or contributed to a spate of alleged patient complications. Twenty-eight former patients or their families have sued Dr. Sabit in Ventura Superior Court, alleging negligent acts ranging from misplacing implants in their spines to performing surgeries that were unnecessarily extensive. Dr. Sabit has settled 11 of the suits, one has been dismissed and 16 are still pending against him.

Through his attorneys, Dr. Sabit, who is now practicing medicine in Michigan, declined to comment, citing the malpractice lawsuits and California's medical privacy laws. He has denied the suits' allegations in court filings and, in a deposition, blamed a surgeon who recruited him to Ventura for encouraging patients to sue him. Dr. Sabit has sued that surgeon and the Ventura hospital for wrongful termination.

In his malpractice depositions, Dr. Sabit has alternately denied receiving any monetary benefit from the implants he used in his surgeries or said he didn't know whether he did.

However, a person with knowledge of the matter says Dr. Sabit owned one-fifth of a spinal-implant distributor called Apex Medical Technologies LLC from May 2010 to August 2012. Over



that period, which includes eight months of his tenure in Ventura, he received profit distributions from Apex that averaged about \$12,000 per month, this person says.

Dr. Sabit, 39, was born in Kabul, Afghanistan, but his family fled the country in 1979 during the Soviet invasion. In a deposition, he said they lived in a tent in Pakistan for four years until they emigrated to the U.S.

The family settled in Arlington, Va. Dr. Sabit's father, Abdul Jabbar Sabit, got a job as a reporter for Voice of America. He returned to Afghanistan after the fall of the Taliban and served as Afghanistan's attorney general from 2006 to 2008.

Dr. Sabit attended college and medical school at Virginia Commonwealth University and did his neurosurgery residency at the University of Medicine and Dentistry of New Jersey. He was recruited to Ventura by Moustapha Abou-Samra, a Syrian-born neurosurgeon who had practiced in the middle-class community north of Los Angeles for more than three decades.

Dr. Sabit raised eyebrows at Ventura's Community Memorial Hospital soon after he arrived in June 2009. An avid weight lifter, he said in one of his malpractice depositions that he used supplements such as creatine to build muscle mass. People who worked with him say he was physically intimidating. In the operating room, he played loud heavy-metal music, several hospital nurses have testified.

At first, Dr. Abou-Samra portrayed his recruit as a young star on the cutting edge of neurosurgery who could perform sophisticated spinal procedures CMH had previously been forced to refer out

More

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to academic medical centers, several Ventura doctors say. Dr. Abou-Samra didn't return calls for comment. A spokesman for CMH declined to comment for this article.

Though he was fresh from his residency, Dr. Sabit said in a deposition that he quickly became one of the hospital's busiest surgeons and was billing four times as much as Dr. Abou-Samra within a year. He said this created tensions with Dr. Abou-Samra. During 18 months at CMH, Dr. Sabit performed 371 procedures, including 306 spine operations, according to a list of his cases the hospital provided in the malpractice litigation.

Dr. Sabit prided himself on working fast, according to Joan Kruse, a CMH nurse deposed in the malpractice litigation. "He would grab instruments. He'd shove them into the wound," she testified. "I've never seen any neurosurgeon be that rough and brutal with" tissue "that close to the spinal cord," she said.

In one of his depositions, Dr. Sabit said he found Ms. Kruse to be "very disagreeable" and had asked that she be barred from his surgeries.

Dr. Sabit used a variety of spinal implant brands during his time at CMH, Marilyn Harris, CMH's director of surgical services. In her deposition in the malpractice litigation, Ms. Harris said the switch prompted speculation at the hospital that Dr. Sabit had joined a POD and was profiting from his use of Apex implants.

Dr. Sabit denied to Ms. Harris that this was the case, and later testified he couldn't recall when he began being part of a POD. He testified that he showed up in her office unannounced and told her: "I don't even know what a POD is. I'm not part of a POD." Ms. Harris said "he was in a heightened state of anxiety" and "very emphatic."

However, a person with knowledge of the matter says that Apex was in fact a POD and that Dr. Sabit purchased a one-fifth stake in it in May 2010, after a short trial period.

Apex was created by two men, Adam Pike and Bret Berry. Following a model they replicated at least 11 times across six states, Messrs. Pike and Berry recruited Dr. Sabit and a neurosurgeon in Los Angeles to become partners with them in Apex. Each surgeon bought a 20% interest in the company, with the remaining 60% going to Messrs. Pike and Berry and one of their business associates.

The two men are veterans of the medical-device industry who partnered up to create their own spinal-implant company, Reliance Medical Systems. From offices in Bountiful, Utah, Reliance contracts with machine shops to manufacture replicas of bigger companies' products that it sells under its own brand. The practice is legal under a streamlined FDA approval process for medical devices deemed "substantially equivalent" to ones already on the market.

To get their products adopted, Messrs. Pike and Berry created a series of distributorships similar to Apex and sold ownership stakes to groups of surgeons across the country, according to a person familiar with the operation. Each surgeon received a monthly profit distribution, this person said. The more Reliance implants the surgeons put in patients' backs, the more business their distributorship did and the more they earned.

Under California's anti-kickback statute, it is illegal to pay doctors to induce patient referrals, or for doctors to accept such payments. The practice is also illegal under federal law if the patients are insured by health programs such as Medicare. According to the people familiar with its civil probe, the Justice Department is examining whether the distributorships Messrs. Pike and Berry created were effectively kickback mechanisms to induce surgeons to use Reliance implants.

The answer to that question hinges in part on whether the amount Dr. Sabit and the other surgeons paid for their distributorship stakes is too small to be considered a real investment, given the size of their returns, which in some cases reached \$50,000 a month.

Federal prosecutors are looking into whether Dr. Sabit's financial interest in Apex made him more prone to operate or to do bigger and riskier surgeries than necessary, the people familiar with the matter say.

The printout of Dr. Sabit's surgeries at CMH shows that, before allegedly switching to Apex, he averaged 14 spine procedures a month and spine surgeries accounted for 76% of his operations. After he allegedly switched to Apex, he averaged 22 spine procedures a month and their share of his case load rose to 87%.

In a court filing, Dr. Sabit has pointed to deposition testimony from CMH Chief Executive Officer Gary Wilde, in which Mr. Wilde stated, "we believed that the vast majority of cases Dr. Sabit did were appropriate."

It is unclear how many patients Dr. Sabit used Apex implants on. Of the 28 patients who sued, he implanted Apex hardware in 12 of them, according to the malpractice depositions and people familiar with the matter. None of those suits allege that the Apex implants were defective.

A spokesperson for Reliance says the fact that Dr. Sabit didn't use Apex on more than half of the plaintiffs shows that there is no causal relationship between his use of Apex and the suits. "It is wholly inaccurate to assume that these claims are a result of the use of Apex products. To the best of our knowledge, there have never been any allegations by patients or doctors about faulty Apex products," the spokesperson said.

One of the patients Dr. Sabit operated on using Apex was Guanda Dusette, a 72-year-old retired nurse. Jack Padour, Ms. Dusette's primary-care doctor, says he referred her to Dr. Sabit after she complained of persistent back pain. Dr. Sabit proposed removing part of two disks in her spine, a relatively routine procedure designed to take pressure off the nerve root, Dr. Padour says.

Dr. Sabit operated on Ms. Dusette on July 8, 2010. However, the surgery he performed turned out to be much more extensive: Using Apex implants, he fused together eight vertebral levels in her spine, Dr. Padour says.

After the surgery, Ms. Dusette was "in agonizing pain," according to Dr. Padour. The metal screws and rods Dr. Sabit had drilled into her spine began coming loose, and the rods pressed against the skin of her back from the inside, according to Dr. Padour and Ms. Dusette's attorney.

Ms. Dusette was re-operated on at Cedars-Sinai Medical Center in Los Angeles, where all the hardware Dr. Sabit implanted was taken out, Dr. Padour says. She subsequently sued both Dr. Sabit and CMH. She recently reached a confidential settlement with the hospital, but her case against Dr. Sabit is still pending. Dr. Sabit has denied her suit's allegations.

Outside the hospital, Dr. Sabit's surgical outcomes caught the attention of Gary Proffett, the medical director of a physician association called SeaView that coordinates patients' care on behalf of health plans. Of 75 SeaView patients operated on by Dr. Sabit over his 18-month tenure in Ventura, 28 developed major complications, including two who died, Dr. Proffett said in an interview. Dr. Proffett reported the SeaView complications and deaths to the California Medical Board.

Many of Dr. Sabit's post-surgical complications involved infections, according to depositions by several nurses and Cary Savitch, an infectious diseases doctor at CMH.

Dr. Sabit has disputed this. In a court filing, he said CMH's infections control nurse "performed an exhaustive review of my infection rate" and concluded that it "was normal and acceptable."

One alleged victim of infection was Lillian Kaulback, an overweight woman in her late 60s with a number of health issues, ranging from diabetes to a history of ankle, shoulder and knee surgeries. Dr. Sabit operated on her on Oct. 7, 2010, using Apex implants to fuse three vertebral levels in her spine, according to several people familiar with her case.

A person close to Ms. Kaulback says she was mobile and active before her surgery, playing bingo, attending family functions and going to a local club to watch couples dance. After the surgery, she never walked again and was in and out of the intensive care unit, this person says.

Dr. Savitch, who treated Ms. Kaulback after her surgery, recalled in his deposition that she had a big wound on her back that "was open" and "dripping pus" and had "six different bugs growing from" it.

To his astonishment, Dr. Sabit closed the infected wound and didn't document it in Ms. Kaulback's medical chart, Dr. Savitch testified. "Whenever you have an infected wound, you need it to drain... The last thing you do is close it," he said.

The wound opened back up the following day, according to Dr. Savitch's deposition. The person close to Ms. Kaulback says she was eventually transferred to a nursing home, where she spent six months in acute pain. She died there on May 31, 2011.

Ms. Kaulback's son has filed a wrongful-death suit against Dr. Sabit and CMH. The case is pending. Dr. Sabit and CMH have denied the suit's allegations.

In their depositions, Ms. Kruse and other nurses testified that Dr. Sabit was cavalier about keeping the operating field sterile and would sometimes contaminate it by not scrubbing in properly or by letting his hair dangle over an open wound.

The Reliance spokesperson said, "There is absolutely no connection between allegations of infection and Reliance's products or its sterilization procedures."

When CMH confronted him about alleged post-surgical infections among his patients, Dr. Sabit blamed one of the hospital's two operating rooms, which he argued in a letter wasn't kept sufficiently clean and sterile.

On Dec. 3, 2010, CMH suspended Dr. Sabit. Mr. Wilde, the CEO, handed him a letter stating that the hospital had decided "immediate action must be taken to protect the life or well-being of patients." The letter said the suspension was based in part on Dr. Sabit's alleged negligent treatment of two unidentified patients. In a subsequent court filing, a senior CMH staffer said one of those two patients died.

Dr. Sabit filed his own statement with the court in which he denied being negligent and said "there was no medical basis at all for the summary suspension." Instead, Dr. Sabit wrote, Dr. Abou-Samra and the hospital had conspired to suspend him so Dr. Abou-Samra could fire him and "avoid paying me the huge bonuses he would otherwise have to pay."

After Dr. Sabit threatened to sue the hospital, CMH reinstated him on Dec. 7, 2010. But Dr. Abou-Samra refused to let him rejoin his practice, so Dr. Sabit voluntarily resigned his hospital privileges on Dec. 21, 2010.

Following Dr. Sabit's departure, the California medical board launched an investigation, according to several CMH doctors and nurses interviewed by the board. A spokeswoman for the medical board declined to comment. The FDA also sent investigators to Ventura and audited Reliance's operations in Utah in May 2011. The results of the audit weren't made public. The Reliance spokesperson said: "Our products, which are certified by a third-party, meet the strict sterilization procedures and protocols established by the FDA."

Reliance discontinued its relationship with Dr. Sabit in August 2012 and stopped operating Apex as a POD, according to a person with knowledge of the company's operations. It has since bought out the ownership interests of surgeons in its other PODs but continues to pay many of them consulting fees, this person says.

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